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RISK ANALYSIS RELEVANT FOR LASER PRODUCTS UNDER IEC 60825-1

Paper #601

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Abstract

While there are deterministic rules laid down in IEC 60825-1 regarding how to determine the accessible emission for the nominal output and classify a laser product, there are also aspects where a probabilistic risk analysis is important. With the revision of IEC 60825-1 (third edition), the role of risk analysis will be emphasized and somewhat widened. Examples where risk analysis plays a role are: is a single fault relevant for classification (i.e. reasonably foreseeable); is additional functional safety (automated power reduction for case of fault) needed; is it permitted that automated power reduction is not fast enough to assure AEL is not exceeded; design of scanning safeguards; and reliability of interlocks. Also, independent of the above issues of functional safety, it should be noted that governmental market surveillance agencies in Europe use risk analysis to decide if a product (such as a Class 3R laser) is acceptable to be marketed as consumer product or not. In this paper, the principles of risk analysis will be discussed as well as examples given where risk analysis has an important role for the manufacturer of a laser product. This paper offers a first input to develop guidance how risk analysis and IEC 61508 in particular can be applied in the design of a laser product.

Introduction

Laser products are classified on an international level according to the international laser safety standard IEC 60825-1 [1]; in the USA, the Center for Devices and Radiological Health (CDRH) also accepts IEC classification according to Laser Notice 50.

According to IEC 60825-1, the basic rules to determine the class of the product, i.e. the accessible emission and the limits for the class (accessible emission limits, AEL) are deterministic, so that the class of the laser product quite often does *not* very well characterize the risk that is associated to the product for normal operation (because, for instance, the accessible emission is determined at a distance of 10 cm from the product/reference point). However, the requirement that the accessible emission of the product shall not exceed the AEL of the class of the product for any reasonably foreseeable single fault introduces a probabilistic (and risk analysis) component, which is often not appreciated. A certain single fault, such as that the current of a laser diode being higher than specified because of an electronic fault, needs to have a sufficiently low probability to be characterized as "not reasonably foreseeable" so that the classification would not be based on the emission level during the fault but on the power that the product is designed to emit (or additional function safety element, such as an active monitoring, is needed). Thus the impact of a probability/risk analysis of the single fault can be significant: either the product is classified based on the regular emission, such as 1 mW (when no single fault is reasonably foreseeable that would lead to higher emissions) and would be Class 2, or – if no additional function safety/active monitoring is realized - on the single fault emission which could make it for instance into a Class 3B product, even if the product for normal operation does not emit more than 1 mW.

The component of probability has been contained in the classification procedure in previous and current editions of IEC 60825-1. In the upcoming third edition of IEC 60825-1, it is "officially" extended to a full risk analysis, including accounting for injury thresholds.

The Principles of Risk Analysis

The discipline of risk analysis is well developed for many years and is discussed in numerous text books (such as [2]) as well as in technical standards and guidance for product design (see for instance [3,4]). The principle of characterizing risk in a quantitative way is well established (often referred to as probabilistic risk analysis, PRA) as a combination of the probability that a "negative event" (such as an injury) occurs, and the graveness of that negative event such as the severity of the injury. The question is then, if the level of risk is tolerable or not. For a product, if the risk is not tolerable, the design of the product needs to be changed to reduce the risk. This principle is for instance laid down in ISO/IEC Guide 51 [5], which gives guidance for the development of product safety standards, to perform a risk analysis and define risk reduction measures so that the residual risk is tolerable. A very similar concept for the reduction of risk (the residual risk) to below the tolerable level is given by IEC 61508-5 (Fig. 1) where the component that is used to reduce the risk of the overall system is referred to as safety-relevant system [6]. The necessary risk reduction is the result of such an analysis and yields the necessary safety integrity level (SIL) of the safety-

relevant system. It should be noted that IEC 61508 in the strict sense only applies to functional safety, such as interlocks, scanning safeguards or power monitoring, and not in the general sense of safety engineering such as design of guards to withstand a certain level of laser radiation.

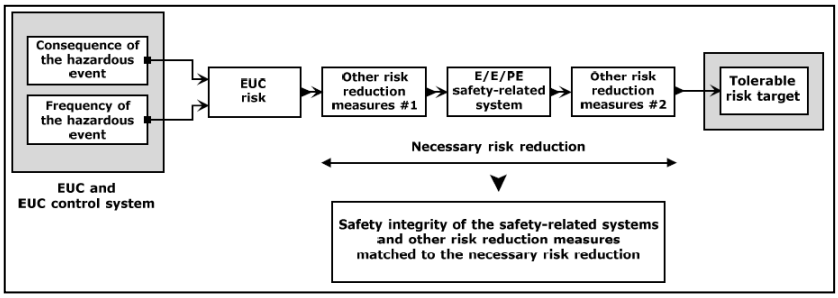

Fig. 1. The process of risk assessment and reduction to a tolerable level with a safety-related system as defined by IEC 61508. EUC is the equipment under control, i.e. the product.

The level of quantification and sophistication in a risk analysis can vary. Very common and relatively simple is the categorization of probability and severity in a matrix method, for instance as shown in Fig. 2 which is copied from a European Commission official guideline for product safety market surveillance analysis [7]. A very similar matrix scheme is given in IEC 61508-5 as an example for risk classification (Table C.1).

Risk level from the combination of the severity of injury and probability

Probability of damage during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
High	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

Fig. 2. Example of a matrix risk characterization scheme, from a European decision on consumer product safety.

In the EC decision, the severity of injury is specified with four categories, from 1 to 4 and examples are given for a list of types of injury. For "eye injury", the severities are: 1: temporary pain in eye without need for treatment; 2: temporary loss of sight; 3: partial loss of sight, Permanent loss of sight (one eye); 4: permanent loss of sight (both eyes). It can be assumed that injury severity category 2 (temporary loss of sight) means an actual injury (with need for treatment), not just transient visual effects from bright light such as flash blindness. Thus for laser induced retinal injury it would follow from the view point of the author that if retinal injury occurs, it is usually of severity category 3. A mild photokeratitis could be 1, with a more severe one, where vision is compromised for 2-3 days, should be an example of category 2. The level of risk (as a result of the combination of probability and severity of injury) is categorized into four categories: low, medium, high and serious. The follow up action (such as enforcing withdrawal of the product from the market, requiring additional warning) then depends on the level of risk.

Of course the manufacturer can use the scheme also (before the market surveillance authorities become active) to decide on the design of the product and of warnings. While the categorisation varies for different guidelines and industry sectors (as will the tolerable risk vary between toys and industrial machines), the principle of the matrix method to determine if risk is tolerable (lower left triangle part of the matrix) or not (upper right triangle part) is widespread.

For a more specific risk analysis, such as for the question if a Class 3R laser product presents a tolerable risk or not, the range of severity of the injury is not so wide as to necessitate a matrix method. The severity of injury is either an injury of the retina, or no injury if the exposure even for rather worst- case assumptions is below the injury threshold. Thus the remaining parameter that needs to be specified is the probability that expsoure above the injury threshold occurs, which depends on the emission of the product but also on pupil size, distance of the product and exposure duration [8].

What is "Acceptable Risk"?

The question remains when a risk, in the above example, the probability for a retinal injury, is tolerable and when it is not tolerable (for instance so that the product can not be marketed as consumer product for instance). The laser safety standard does not give guidance on this question. The EU guidance document [7] also stops at the level of determiantion of the level of risk, and says that the follow-up action needs to be decided in the process of risk management that follows the risk asessment. IEC 61508 will be discussed below.

For a general characterization of what risk is usually seen as acceptable (or "tolerable"), the autor has identified relevant numbers in the literature for a PRA project on laser satellite missions of the European Space Agency [9]. In risk analysis, individual risk and global risk is distinguished. Individual risk is the probability for a certain level of harm to occur per hour (or some other temporal unit) of activity, such as using a product or doing some sports, or flying in an airplane. If the risk is specified as "probability per

hour" (or another time unit) then this can also be referred to as "frequency". The European Commission guideline uses the probability of damage occuring with the temporal quantification of "during the lifetime of a product". Individual risk can also be characterized not specifically for a certain activity but generally to occur for an individuum per year (which might then scale with the time spent following a certain activity, so it is a less direct measure). Global risk on the other hand (also called collective risk) characterises the overall number of injuries (or occurances of an accident, such as a atomic power plant core melt-down), for instance world-wide per year. Whenever the probability unit is specified as for instance 10^{-5} per year probability that a core melt-down occurs, this figure can also be communicated as one melt-down every 100 000 years (which by the way is a figure that is usually considered as acceptable [10]). Also one needs to consider if the activity is voluntary or not. It is generally known that far higher risks are accepted for voluntary activities than for involuntary activities. The results by Starr [11] indicate that the level of acceptance for voluntary risks is a factor of 1000 higher than the level of acceptance of involuntary risks.

Since the data regarding the risk for the loss of life is more extensive than for injuries, it lends itself to discuss this first and then to scale this to injuries such as the loss of an eye. For instance, Starr [12] reports for involuntary risks, the general level of acceptance in the US population is 10^{-6} per person per year for the loss of life, comparable to the "background" risk of being killed by natural phenomena such as lightning or floods. For an acceptable level of risk for the risk associated with the use of *new technologies*, Starr recommends to reduce the level by a factor of 10 or 100, i.e. 10^{-7} or 10^{-8} per person per year. The level of 10^{-4} to 10^{-6} per person per year is also identified in a European study as usually accepted level of risk, i.e. a risk higher than 10^{-4} is usually not accepted [13].

Also often the background "living risk" is used as baseline for an acceptable risk. For instance, in the Netherlands, the lowest mortality rate is calculated for children in the age of 10 to 15 years as 10^{-4} per year [14] and the Dutch safety policy is such that the individual risk should not increase the background risk by more than 1 %. This calculates to a level of 10^{-6} per person per year. Levels of risk which are often applied as acceptable levels in terms of law cases in the US were researched by Vose [2]:
10^{-4} per person per year for illness
10^{-5} per person per year for permanent injury
10^{-6} per lifetime for death or severe disablement (i.e. roughly 10^{-8} per person per year)

Permanent vision loss for one eye would be expected to fall into the second category; hence an acceptable level of risk which appears appropriate **could be 10^{-5} per person per year.** When the probability for injury per hour of using a certain product is characterized, it depends on the duration of usage of the product per year if this acceptable level is exceeded or not. This level is about a factor 10 - 100 higher compared to the risk level usually accepted for loss of life, which fits quite well with the subjective difference of the *severity* of the injury as listed by Green and Brown [15], where the loss of one eye had a factor of 16 lower severity ranking that loss of life.

Even when the individual risk is below accepted limits, the globally expected number of ocular injuries on a global basis is still of concern for risk management, for instance to characterize the risk for liability. If the accident, such as a nuclear power plant core melt-down affects a larger number of people, then global risk is also an appropriate measure. In IEC 61508, this type of risk figure is referred to as "societal risk". According to an investigation by Starr [16], regarding loss of life, a global risk of 1 to 10 (cases of death) per million people and year is usually considered small, a global risk of 100 per million and year is usually considered a moderate risk. These findings are confirmed by a UK study [17], which arrives at a value of about 2 cases of death per million per year. A relatively low acceptable value is suggested by Wilson and Crouch [18], 10 deaths per year for the US, which recalculates as 0.05 deaths per million and year. When it is appreciated that the severity associated to ocular injury of one eye can be expected to be at least a factor 10 below the loss of life, then the lowest collective risk limit of 0.05 deaths per million and year would re-scale to 0.5 ocular injuries per million per year and the higher figure of 1 death per million per year would re-scale to 10 ocular injuries per million per year.

Also the individual risk numbers of above can be used to infer global risk numbers: an individual risk of 10^{-5} per person per year for permanent injury with the assumption that all of the population is exposed to the same average individual risk (which for laser products is not likely, except they are space based) can be interpreted as one injury in every 100 000 people per year, or 10 injuries per million per year. This number is the same as the less conservative value of the previous paragraph.

Specifications in IEC 60825-1

The relevant wording regarding reasonably foreseeable single faults in IEC 60825-1 Edition 2.0 (the edition valid at the time of writing), is found in clause 9.1:

Tests during operation shall be used to determine the classification of the product. Tests during operation,

maintenance and service shall also be used as appropriate to determine the requirements for safety interlocks, labels and information for the user. The above tests shall be made under each and every reasonably foreseeable single-fault condition.

If a single fault is reasonably foreseeable, the classification is based on the emission that is accessible during the fault, if it is not reasonably foreseeable, then the classification is based on the emission that is accessible during normal operation. The term “reasonably foreseeable” means that it is acceptable that the fault occurs with some finite probability, but that probability has to be correspondingly low so that it can be characterized as “not reasonably foreseeable”. There is no guidance given what level of probability can be seen as “not reasonably foreseeable”, however, in NOTE 3 it is detailed that

Probability analysis may be used to assist in determining "reasonably foreseeable single fault conditions"

and IEC 61508 is given as (non-normative) reference. The concept of reasonably foreseeable faults or conditions is also used in Clause 4.2.1 regarding the protective housing having to withstand exposures under reasonable single fault conditions; in Clause 9.1 it is required that for the test of the protective housing all reasonably foreseeable changes of direction of the beam must be considered.

If the probability of a given single fault is “too high”, i.e. the fault is considered as reasonably foreseeable, technical means have to be realized to reduce the probability of the fault and to assure that the overall risk becomes tolerable. This is done by adding a “safety-related system”, to use the terminology of IEC 61508. In the current edition of IEC 60825-1, this scenario is reflected in Clause 9.1:

However, if the emission is reduced to a level below the AEL by automatic reduction in a duration within which it is not reasonably foreseeable to have human access, then such faults need not be considered.

For a product that is classified based on the scanned emission, according to clause 4.11, a scanning safeguard must reduce the level of emission of a product in case of a scanning failure so that the class limits are not violated, unless (i.e. if the automatic system is too slow) it is not reasonable foreseeable during the short time that the emission exceeds the AEL that exposure of people occurs.

Third Edition

In the third edition of IEC 60825-1, which at the time of writing is in the CDV stage and scheduled to be published by the end of 2013, the role of risk analysis is specified more directly. While in the second edition, IEC 61508 was in a note, it is now in the body of the text (but still not normative, i.e. the manufacturer has the flexibility to apply alternative guidelines for the risk analysis):

The required reliability of the automatic reduction of the emission level to stay within a given class can be assessed on the principles of risk analyses, for instance as described in IEC 61508 where safety integrity levels (SIL) are specified.

The principle of deciding what level of probability is tolerable for a given fault is spelt out and now specifically refers to the risk for injury:

To determine if a single fault condition is considered as reasonably foreseeable or not, both the probability (frequency) for the fault as well as the risk for injury (probability of exposure to a level that could induce injury and severity of injury) is to be considered. The lower the risk for injury, the “more frequent” can the fault (that would result in a given emission level) be allowed. An acceptable mode of analysis of the probability and risk regarding failures are [] the procedures described in IEC 61508.

It should be noted that the basic test requirement as such is not changed in the third edition and the criterion is still, if a single fault is reasonably foreseeable or not. Since Edition 2 already referred to IEC 61508, which was always about designing a product to achieve overall tolerable risk accounting also for the severity of the potential injury, in effect the above principle already was/is inherent in the current edition of the laser safety standard. In the third edition it is emphasized and worded more explicitly. It is also noted that the addition of an appendix was considered during the development phase of the third edition, as making the usage of risk analysis more “spelt out” and adjusting the text to that state of the art was also driven by IEC TC66 represented by Hermann-Josef Boch. A draft informative appendix was supplied by IEC TC66 which intended, for instance, to link the required SIL of interlocks for embedded laser products to the class that the embedded laser would have on its own (without interlocked protective housing). However, as the risk that is associated with a given laser even within a certain class varies so widely, and because a detailed consideration of what for laser is a severe, etc. injury, it was difficult to develop that annex within the given time schedule. Also the tolerable residual risk will vary strongly, depending on type of product (industry sector). Therefore such an annex is not included in the current draft, but is intended to be added after the publication of Edition 3 as an amendment.

Legal Motivations

Besides the role in IEC 60825-1 for the classification of a laser product, risk analysis has obviously a more general basis for product design. ISO/IEC Guide 51 (1999) for some time specifies risk analysis as the basis for developing product safety standards. In Europe, the General Product Safety Directive requires that a consumer product needs to be “safe” which is then in principle defined to mean “not hazardous”. The European Commission guidance document discussed

above makes it clear that the basis for decision what product is "safe enough" is risk analysis. Since the market surveillance officials use this principle to decide if the sale of a certain product is to be restricted, it lends itself to be used by the manufacturer in the first place to design a safe product where the "risk" for actions by the market surveillance officials is low (here the risk is also a combination of probability of occurrence and severity of the action, such as required recall from the market as most severe consequence). This is also the basic concept of IEC 61508, i.e. to analyze the risk of a product without functional safety features and to reduce the risk to below a tolerable level with the implementation of safety-related systems.

An analysis of the probability of injury or other damages to occur is also part of the management of liability. Liability becomes relevant if an injury or damage occurred and the victim sues for compensation. In many countries such as the US, Europe and Japan, there is a system of strict tort, so that a manufacturer is liable even if it is not his "fault", so that "compliance with a standard" is no line of defense, because if the product is considered as "faulty", the manufacturer is liable even if he did "whatever he could" (for the design of the product) to make it safe. If a Class 2 laser has a faulty power limitation and the product causes an eye injury (and the victim sues for compensation), it does not help the manufacturer to argue that this scenario was highly unlikely and the product complied with a technical standard (there are many cases where the manufacturer was liable even though the product complied with a standard). However, an analysis of the probability for injury and therefore the probability for liability is the tool to measure the liability risk. Also, performing a risk analysis and reducing the risk for injury by design shows that the manufacturer was diligent so that the compensation is covered by the insurance (which is not the case for gross negligence) and there is also strongly reduced risk for being punished under criminal law.

IEC 61508 on Functional Safety

IEC 61508 is one of the main standards on risk analysis regarding functional safety, and is the main one for electric and programmable systems. A detailed discussion of IEC 61508 is out of the scope of this article, and there are text books available [3]. Exemplary schemes of how to deal with the principles of the IEC 61508 series are given in IEC 61508-5. It should be noted that this standard series was developed to define the principle requirements and not to give specific numbers, i.e. the methods given in Part 5 are only "examples" and details will depend on the type of product/sector. Along those lines, the standard is a horizontal standard with the function that other, sector specific, standards adopt the method. This is for instance the case with ISO 26262 for the automotive industry. For machines, ISO 13849 is the standard on risk analysis and instead of SIL defines required PL (performance level) for the functional safety.

IEC 61508 is to be applied in the conceptual phase of the design of the product. The risk that is associated to the product assuming that there is no safety-related system is to be characterized. For laser products, a safety-related system would for instance be an interlock or a scanning safeguard or an automated power reduction for fiber breakage. If the risk is not tolerable without the safety-related system, a safety-related system is needed to reduce the risk to below an acceptable level. It is clear that also the safety-related system needs to have a level of reliability. The higher the risk is in the scenario that there is no safety-related system, the higher the reliability of the safety-related system has to be. This is characterized by the required SIL of that component, where SIL stands for Safety Integrity Level. For instance, for an interlock for an embedded laser product classified as Class 1, the interlock would have to have a higher SIL if the embedded laser is a kilowatt laser as compared to a 10 mW laser diode.

Injury Threshold vs. MPE, Class 3R

The MPE for the eye and the skin is a relatively simple baseline for risk analysis, at least when the exposure is below the MPE. Then one can characterize the risk for injury as "negligible", unless for very rare extreme cases of hypersensitivity, such as when special photosensitizers (for medical procedures for instance) are involved. Since Class 1 and Class 2 are based on that level, the laser product classification is also a simple way to characterize the risk for worst-case exposure distances. In an MPE analysis, more realistic distances and exposure durations can be considered, so an MPE analysis is one level higher, or more "accurate" (in the sense of specific), than just classification. The third level of sophistication is to consider actual injury thresholds rather than MPE values. This, however, needs reliable data on the one hand as well as experience and expertise regarding the application and interpretation of the data. Often it is assumed that the reduction factor (also referred to as **safety factor**) between the injury threshold and the MPE is generally **10** (see also a presentations in these proceedings). It cannot be emphasized enough that this is generally ***NOT the case***! There are many cases (combinations of wavelength, spot size, pulse duration, exposure duration, number of pulses) in Edition 2 and especially in the next edition of IEC 60825-1 where the reduction factor is as small as 2.5. A detailed

discussion is not possible here, as the reduction factor cannot specified without discussing the endpoint that is associated with the injury threshold, i.e. "what" is actually considered as threshold and how it is determined [19]. For instance, many publications, particularly in early days of retinal injury threshold research, use an endpoint of examining the eye 1 h after exposure. However, the injury often takes some time to develop at least in terms of visibility with an ophthalmoscope, so that the injury (even though already existing on the retinal level) is not visible ophthalmoscopically after 1 h. When an endpoint of 24 h is used, which is the practice of later experimental studies (additionally to the 1 h endpoint), injuries can often be detected at lower exposure values than compared to the 1 h endpoint, particularly for instance for nanosecond pulse durations. Thus, the 24 h value is often significantly lower than the 1 h value. This is a reason why for a very special case of 532 nm wavelength, single pulses in the 1 – 10 ns range and 80 µm spot size, there is ***no reduction factor*** between the current MPE and rhesus ED50 data for the 24 h data. This means that the current MPE is too high, having been based on 1 h data, and this is the reason why the retinal MPE system needs to be revised, as reviewed by Schulmeister et al. [20]. Also potential experimental uncertainties need to be considered, so that it is beneficiary to know the general quality of the work that a certain laboratory has produced, and it is vital to compare a certain study with the results of others with comparable parameters or with parameters (wavelength, pulse duration, spot size) that can be extra/interpolated. Since the MPEs in terms of dependence on pulse duration, wavelength and pulse pattern are a simplification of the respective biological injury thresholds dependencies, the reduction factor varies depending on pulse duration (often it is lowest in the millisecond range and higher for longer (200 ms) and shorter (1 µs) pulse duration range; also the green wavelengths often have lower reduction factors than for instance blue or red wavelengths, etc..

The Seibersdorf Laboratories invested more than 10 man-years for the research, development and application of a data base and computer model for ocular and skin injury, where the model on retina and the skin are presented in these proceedings (#1002, #P105), the model for the cornea was presented at ILSC 2011 [21]. A considerable part of the changes to the retinal MPEs promulgated by ICNIRP and adopted by IEC 60825-1 is based on that experimental and computer modeling work. With retinal injury threshold data, it is possible to perform a risk analysis, such as discussed for the case of continuous and collimated emission in the visible wavelength range in the power range of Class 2 and Class 3R [22]. As an example, it could be shown (what is also known from experience) that a 2 mW red cw laser with a collimated beam (Class 3R) can be said to be below injury thresholds including some reduction factor and therefore associated with practically no risk for retinal injury.

It is also emphasized again that this conclusion of "negligible or very low risk" cannot generally be associated with Class 3R especially in the third edition of IEC 60825-1 [8]. There are many cases where the reduction factor will be of the order of 3 or somewhat less, so that the probability for injury cannot generally be said to be "negligible" (approaching zero) when the emission of a laser product is 5 times the MPE, i.e. exceeding the ED50 (50% injury threshold for rhesus monkeys) by a factor of roughly 2.5. It is of course correct that for larger beam diameters, the pupil size plays a role as well as the accommodation condition of the eye, which reduces the risk for the case of smaller pupils and accommodation conditions that do not image the apparent source, but the risk characterization is not as simple as for exposure below the MPE.

Application of Principles for Laser Products

To clarify the above summary of the principles, and to provide suggestions on how to develop them further into application guidelines for laser products, the following examples are offered.

Risk analysis is relevant for the design of laser products on several levels, from the emission as designed (normal operation) to the reliability of scanning safeguards. The design of laser materials processing machines and guards is also a topic where risk analysis is applied, but not discussed here. It is helpful to organize the types of application of risk analysis for laser products into the following groups:

1. To decide if the nominal output of the device is acceptable to be marketed, for instance as consumer product, or medical product, etc.
2. To decide if a single fault of the device is reasonably foreseeable or not (if it is, the class is based on fault emission or a safety-related system is necessary to reduce the risk)
3. If a safety-related system is installed to reduce the risk (because the risk based on the fault is not tolerable and to avoid having to base the classification on the emission during a fault), to derive the necessary reliability (SIL) for that safety system.
4. For the case that IEC 60825-1 requires a "safety-related system" (a scanning safeguard or interlock for panels), to derive the necessary reliability (SIL)
5. If a safety-related system (see 3. and 4.) is not fast enough to switch the laser power off in time to stay below the AEL for the target class, to decide if this is acceptable.

These different groups of issues, where risk analysis is or can be relevant, will be discussed in the following sub-sections.

8.1 Acceptability for Marketing based on Emission

There are examples where a risk analysis is relevant for the decision if a given product is acceptable to be placed on the market or not – based on the "normal" emission, i.e. the emission as designed. This is the case when the laser safety class of the product cannot be used for that decision. For instance, a Class 3R laser product to be marketed as consumer product can be expected to meet some action by the market surveillance authorities if it cannot be shown that normal operation and foreseeable misuse is "safe", i.e. has an acceptable low level of risk (see EC guidance [7]). Another example is a laser beam emitted from a satellite for instance to measure atmospheric properties; here, the design would usually be such that the MPE for the naked eye is not exceeded, but a risk analysis is needed to characterize if the risk for exposure through telescopes is acceptable (even large telescopes are sometimes used to track satellites); such a risk analysis was developed by the author for the European Space Agency and not only included the estimated probability for ocular injury per mission duration, but also the uncertainty of that figure calculated with Monte Carlo analysis for what is referred a second level PRA [23, 24]. A third example is a consumer product with a highly divergent infrared beam, which is Class 1 but at contact significantly exceeds the exposure limits of the skin. The manufacturer might want to know what the risk for skin injury is for different assumed exposure durations. Also, for a medical product, according to IEC 60601-1 Edition 3, a risk management file is required for each medical product, where the management (including, but not limited to analysis) is to be carried out according to ISO 14971 [25].

In many of above cases, the MPE is exceeded and as a first step, one needs to characterize the level of exposure, or the probability for certain exposure levels and scenarios to occur, considering distance, exposure duration, pigmentation level, pupil size, etc. If for a given exposure scenario, the exposure is below injury thresholds, then the probability for that exposure scenario to occur is no longer an issue and the risk for this scenario is "negligible". If injury cannot be excluded, for instance due to the uncertainty of the injury threshold collection or model, but the probability for the respective scenario is very small, the risk, following a corresponding analysis, could still be considered as acceptable (or tolerable). This analysis does not have to be fully quantitative (as a gold standard even including uncertainty analysis with Monte Carlo analysis), but a matrix method as discussed above can be used.

Since this analysis applies primarily to the *nominal* laser emission as it is designed to function, this type of analysis is not related directly to the classification process according to IEC 60825-1 (as the following sub-sections are), but is called for when the classification according to IEC 60825-1 does not provide the required level of information regarding the risk of injury. When the question is if a certain laser power level is considered acceptable or not, then this is also not about functional safety and the risk analysis is broader than IEC 61508.

In this context, also information for the user is relevant, although safety by design is not only superior to safety by warning and user measures, it is also a legal principle that safety by design needs to be realized first. User information (warning labels, handbook) is not part of safety engineering as such. Safety engineering is about safe product design and reducing the risk to below the tolerable level by design features. Following this principle, it is necessary to supply proper warnings and user information regarding any *remaining risks* unless they are generally known (such as that a knife is sharp), or the probability of the hazard to materialize is small (common for faults). The level of required safety by design and what is acceptable as warning depends on the type of the product: for a toy, the requirements of safety by design are high (tolerable residual risk low) and warning and information for proper use cannot be expected to serve their purpose. On the other hand, professional machines can rely more on warnings and proper behavior regarding residual risks, i.e. the tolerable residual risk is considerably higher as compared to a toy.

8.2 Single Fault (without Safety-Related System)

A risk analysis is performed to decide if a single fault is "reasonably foreseeable". The result of such an analysis determines if the class of a product is for instance Class 1 (based on nominal emission) or Class 3B (based on emission during the fault); or, if Class 1 is to be achieved, an additional safety-related system is necessary. As discussed above, the criterion for classification is if the fault is considered "reasonable foreseeable" or not, which is another way to say, according to the interpretation of the third edition of IEC 60825-1, if the risk is tolerable or not, linking both the probability that the fault occurs as well as the probability that an injury occurs as a consequence of the fault and what the severity of that injury is. An example is a fault in the power control of a laser diode, wavelength 650 nm, with nominal cw emission of max. 0.3 mW, therefore Class 1. During a fault of the diode current limiting resistor, the emitted power could

be, for instance, up to 3 mW. It is generally known that 3 mW red visible has very little risk for injury, as was for instance discussed by Schulmeister and Jean [22]. Thus, for 3 mW cw 650 nm, the risk for injury in case of a fault and continuous emission for an alignment laser for a leather cutting machine where the laser points downwards can be considered to be negligible. For the case of intentional pointing the beam into the eye for an eye diagnostic device, a more detailed analysis of the risk for injury appears prudent before it can be said that this fault is not reasonably foreseeable and the risk is tolerable. This is both a question of classification of the product according to IEC 60825-1 as well as of the decision if the product is generally tolerable in that design (to be placed on the market). Seen from the general side, the question is if the product is acceptable without safety-related system that would reduce the power output to safe levels for the case of a fault; in that sense, if the risk is found to be "not tolerable", a safety-related system would be mandatory according to IEC 61508. According to IEC 60825-1, the consequence of a decision of not realizing a safety-related system is that the product is classified based on the emission during the fault, but it is not mandatory to realize the safety-related system. Thus the product is compliant with IEC 60825-1 when it is classified based on the emission during the fault (for instance as Class 3R, 3B or even 4) and the decision is shifted to the question, if a certain product is acceptable for a given application or not. The reason for this situation is, that compliance with IEC 60825-1 on its own (as Class 3B for instance) does not mean that a product has an acceptable level of safety (for instance as consumer product).

The example of 3 mW laser power was chosen to be able to say that this level, for momentary exposure and even somewhat longer than momentary, can be expected to be below injury thresholds. The situation changes for the case that the power of the beam during fault becomes, for instance, 100 mW, which is known to cause immediate retinal injuries. The "acceptable frequency" for the fault, i.e. a probability so that the fault can be characterized as "not reasonably foreseeable" is thus correspondingly lower than for a case where the emission during the fault can be expected not to cause injury, even for exposure somewhat longer than 0.25 s. The severity of injury can be seen as of level 3 for the European Commission decision, and also 3 for IEC 61508. For the risk to be characterized as "Low" for the European Commission decision, the probability for occurrence has to be less likely than 1 to 100 000 within the lifetime of the product (see Fig. 2).

It is again emphasized that this principle of risk analysis was present in previous and is present in the current edition 2 of IEC 60825-1 in the form of the term "reasonably foreseeable"; it was for instance also discussed for Edition 1.2 in "Laser Safety" by Henderson & Schulmeister. In Edition 2 of IEC 60825-1, the risk/probability principle was included in a footnote, referring to IEC 61508 as a non-normative reference, and IEC 60825-1 is now amended to be published as 3rd Edition to account for the "state of technology" in product safety design, including the reference to risk in the body of the text.

8.3 Safety-Related System; General

For the example a 100 mW emission during the fault and the probability for a fault to occur in the range where it cannot be said to be low enough so that it is not reasonably foreseeable, if it should be avoided that the class of the product is based on the emission during the fault, an automatic power reduction is needed. Such a safety-related system - irrespective of laser safety classification - is also needed according to general product design principles as reflected in IEC 61508 if the risk without the system is not tolerable. Such a system can for instance be a detector that continuously monitors the output power level (or a fraction of it) and reduces the laser power or switches the laser off for the case that the measured power exceeds a critical level.

It is permitted under IEC 60825-1 that the emission of the product, when the fault occurs, is for a short time above the AEL of the class of the product, when the associated risk is correspondingly small, i.e. tolerable. In the current edition of the laser standard, the respective permission refers to the probability for exposure during the higher emission, but the general product design principle of tolerable risk (wider as just the probability) also applies here. The risk associated to the period of higher emission can be small, either because the higher emission is unlikely to cause injury (below injury level), or because the probability for exposure with a critical scenario (distance, pupil diameter) is small, or both. When it can be shown that exposure during that period is below injury thresholds, then the risk is negligible irrespective of the probability of exposure; this has the advantage of not having to rely on the argument that the probability is small, which is often difficult to characterize.

The concept of IEC 61508 goes beyond the specific requirements of IEC 60825-1 for the classification of a laser product, as it requires a certain SIL (comparable to a reliability level) for the safety-related system. According to IEC 60825-1, it is only single faults which are specifically mentioned and when there is a safety-related system, two faults would need to occur for the higher emission, i.e. the primary fault of the laser product (for instance shortening of resistor) as well as the fault of the safety-related system (automatic

power reduction). The assessment of the probability of failure of the safety-related system is not specifically required by IEC 60825-1, but is part of the system developed in IEC 61508. It should be emphasized again that IEC 60825-1 Edition 3 does not list IEC 61508 as normative reference and specifically says that a full analysis according to IEC 61508 is not necessary (which can be a very involved project) as well as that other risk analysis schematics can be used. The overall goal of a safety standard is however clear: the risk associated with the product needs to be acceptably low.

8.4 Scanning Safeguard

For a scanned emission, IEC 60825-1 specifies that classification can be based on the scanned emission, if a scanning safeguard is in place that functions as automatic power reduction for the case that the radiation is no longer scanned (a fault of the mirror-motor for instance). Thus in the sense of IEC 61508, the scanning safeguard is a safety-related system. It is interesting to note that if a safety-related system needs to be installed or not depends according to IEC 61508 on the risk during the fault. Thus, for instance, if the risk that is associated to the stationary beam is tolerable, IEC 61508 would not require a scanning safeguard. An example is a beam power of 1 mW, or 2 mW for a red laser where the stationary beam can be characterized as not to exceed injury thresholds and the risk would therefore be negligible even without a scanning safeguard. However, irrespective of that general principle, IEC 60825-1 (also Ed. 3) requires a scanning safeguard to be in place also for the above cases. However, the principle of risk analysis can again be applied for the case that the scanning safeguard is not fast enough to reduce the power to below the AEL of the associated class of the product (see previous clause), as well as regarding the analysis how reliable the scanning safeguard has to be. When the emission level of the beam when it becomes stationary (and the scanning safeguard would not function) is below injury levels, the required reliability is rather low or the tolerable frequency that the scanning safeguard does not function is high, as according to IEC 61508, there is no additional safety requirement necessary.

8.5 Interlock

The interlock for an access panel is required in IEC 60825-1 when classification is to be based on the prevention of access of the radiation by the housing. The interlock is a safety-related system; according to the principles of IEC 61508, the risk analysis of the product without interlock results in the required risk reduction, and SIL of the interlock. An appropriately rated interlock can then be selected. IEC 60825-1 requires a “failsafe” interlock, however, in the CDV of Edition 3, a note specifies that the required reliability can be determined according to the principles of IEC 61508 or ISO 13849.

The interlock would lend itself as issue where guidance on the selection of the required SIL can be based on the laser class of the embedded laser, as the class can give an indication of the severity of the injury. Corresponding guidance, not only for the interlock, is to be included in an amendment.

Conclusions and Summary

Risk analysis has been part of the classification in previous and current editions of IEC 60825-1 mainly in the form of the requirement that testing for classification has to include reasonably foreseeable single faults. If a single fault is considered as reasonable foreseeable, i.e. the frequency of occurrence exceeding a critical level, and no additional safety-related system is in place, the class would characterize the emission under fault and not the nominal output power. What level of frequency of the fault is considered as reasonably foreseeable, and what level is considered as tolerable so that the fault would not have to be considered for classification (or a safety-related system installed alternatively), can be determined with risk analysis. Also risk analysis becomes important when a safety-related system, such as a scanning safeguard, is too slow to prevent emission above the AEL, to characterize if this is acceptable. As a possible method for analysis, IEC 61508 is already referred to in the current, 2nd edition of IEC 60825-1. In the upcoming 3rd edition, the role of risk analysis is made more specific and risk for injury is specifically mentioned.

The concept of classification according to IEC 60825-1, however, is somewhat inconsistent with general product safety requirements, as it is not required that a certain type of product, such as a consumer product, shall not exceed a certain class. A Class 4 open beam laser product also complies with IEC 60825-1, however, would not be acceptable as consumer product. This was pointed out before and is also pointed out in the scope of IEC 60825-1. While according to a risk analysis, for a product with nominal Class 1 emission and a reasonably foreseeable fault that leads to hazardous emission would require installment of a safety-related system (automatic power reduction), IEC 60825-1 can also be satisfied by assigning a higher class to the product. Of course, some classes would not be acceptable for certain products and there is a high motivation for the manufacturer to base classification on the nominal output and not on the output during the fault, but this issue needs to be kept in mind when guidance is developed.

Risk analysis (if the national legal system is not based on the laser class and allows that freedom) can answer the question if a certain product is acceptable to be marketed based on product safety legislation; and it is also the tool to gauge the risk for liability. Such an analysis is not centered, at least not mainly, on a fault condition but on the nominal output and becomes relevant if the information that is conveyed by the class of the product is not sufficient.

In future amendments of IEC 60825-1 Ed. 3, it is planned that guidance for the application of risk analysis is included in an annex.

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References

[1] IEC 60825-1 Ed. 2.0 (2007) Safety of Laser Products – Part 1: Equipment classification and requirements

[2] Vose D., Risk Analysis, 3rd ed. John Weiley, 2008.

[3] Functional safety; (2007) Josef Börcsök, Hüthig Verlag Heidelberg

[4] Smith D., Simpson K. (2010) Safety Critical Systems Handbook; Butterworth-Heinemann

[5] ISO/IEC Guide 51 (1999) Safety aspects – Guidelines for their inclusion in standards

[6] 61508-5 Ed 2.0 (2010) Functional safety of electrical/electronic/programmable electronic safety related systems

[7] European Union Commission Decision 2010/15/EU, Risk Assessment Guidelines for Consumer products, page 33 - 64

[8] Schulmeister K The widely varying risk from Class 3R laser products in light of the revision of IEC 60825-1; ILSC 2011 Paper 103, p.72-75

[9] Schulmeister, Sliney, Mellerio, Hödlmoser, Sonneck; ESA Report Human Risk Analysis Simulator for Space Lidars (2001)

[10] Bedford T. and Cooke R. M., Probabilistic risk analysis – Foundations and Methods, Cambridge Univ Press, 2001.

[11] Starr C., Social benefits vs. technological risk; what is our society willing to pay for safety? Science 165, 1232-1238, 1969.

[12] Starr C., Benefit-Cost Relationships in Socio-Technical Systems, Proc. IAEA Symposium on Environmental Aspects of Nuclear Power Stations, 895-916, New York, August 1970, IAEA-SM-146/47, 1970.

[13] EU, Nuclear and non-nuclear risk – An exercise in comparability, Final Report, Pollution Prevention (Consultants) Ltd, Crawley, England, EUR 6417 EN, 1980.

[14] Versteeg M. F., External safety policy in the Netherlands: an approach to risk management, IAEA-TECDOC 524, Vienna, 1989.

[15] Green C.H. and Brown R.A., Counting Lives, Journ. Occupational Accidents 2, 55-70, 1978.

[16] Starr C., Rudman R, Whipple C, Philosophical basis for risk analysis, Annual Review of Energy 1, 629-662, 1976.

[17] Mole R. H., Accepting risks for other people, Proc. Royal Society of Medicine 69, 107-113, 1976.

[18] Wilson R. and Crouch E., Risk/Benefit Analysis, Ballinger Publ. Co., Cambridge, Mass., 1982.

[19] Sliney DH, Mellerio J, Gabel VP, Schulmeister K. (2002) What is the meaning of threshold in laser injury experiments? Implications for human exposure limits. Health Phys 82:335-347.

[20] Schulmeister K, Stuck BE, Lund DJ, Sliney DH, Review of thresholds and recommendations for revised exposure limits for laser and optical radiation for thermally induced retinal injury; Health Physics 100, 210 - 220; 2011.

[21] Schulmeister K, Jean M (2011) Modelling of laser induced injury of the cornea; ILSC 2011, p. 214-217

[22] Schulmeister K., Jean M. (2010) The risk of retinal injury from Class 2 and visible Class 3R lasers; Medical Laser Application 25, 99–110.

[23] Schulmeister K, Hödlmoser H, Mellerio J, Sliney DH, Second Order PRA Model for Ocular Laser Damage Proceedings ILSC 2003, LIA, p 229-237

[24] Schulmeister, Sonneck, Rattay, Hödlmoser, Sliney, Mellerio, Culoma, Preyssl (2002) A Probabilistic Risk Analysis Model for Receiving Laser Eye Injury from Space Based Lasers; ESA SP-486, Proc Joint ESA NASA Space Flight Safety Conf, Noordwijk, p. 109 - 113

[25] ISO 14971 (2012) Medical devices. Application of risk management to medical devices

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